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In re Application of :
Bernd Sundermann et al :
Serial No.: 10/644,981 : PETITION DECISION
Filed: August 21, 2003 :
Attorney Docket No.: 029310.52539 :

This is in response to the petition under 37 CFR 1.144, filed March 22, 2006, requesting withdrawal of an improper restriction requirement.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111 and contained 36 claims, as filed. The examiner mailed to applicants on March 31, 2005, a restriction requirement, as follows:

Group I – claims 1-36, drawn to compounds of formula I where R_2 is alkyl, cycloalkyl or aryl and neither R_3 and R_4 nor R_5 and R_6 form a ring and A is heteroaryl;

Group II – claims 1-36, drawn to compounds of formula I where R_2 is alkyl, cycloalkyl or aryl and neither R_3 and R_4 nor R_5 and R_6 form a ring and A is not heteroaryl;

Group III – claims 1-36, drawn to compounds of formula I where R_2 is heterocyclic and neither R_3 and R_4 nor R_5 and R_6 form a ring;

Group IV – claims 1-36, drawn to compounds of formula I where R_1 and R_2 form a ring and neither R_3 and R_4 nor R_5 and R_6 form a ring;

Group V – claims 1-36, drawn to compounds of formula I where R_1 and R_2 do not form a ring and R_3 and R_4 form a ring;

Group VI – claims 1-36, drawn to compounds of formula I where R_1 and R_2 form a ring and R_3 and R_4 form a ring;

Group VII – claims 1-36, drawn to compounds of formula I where R_1 and R_2 do not form a ring and R_3 and R_4 form a heteroring (multiheteroring);

Group VIII – claims 1-36, drawn to compounds of formula I where R_1 and R_2 form a ring and R_3 and R_4 form a heteroring;

Group IX – claims 1-36, drawn to compounds of formula I where R_1 and R_2 do not form a ring and R_5 and R_6 form a ring;

Group X – claims 1-36, drawn to compounds of formula I where R_1 and R_2 form a ring and R_5 and R_6 form a ring;

Group XI - claims 1-36, drawn to compounds of formula I where R_1 and R_2 do not form a ring and R_5 and R_6 form a heteroring (multiheteroring); and

Group XII - claims 1-36, drawn to compounds of formula I where R_1 and R_2 form a ring and R_5 and R_6 form a heteroring (multiheteroring).

The examiner set forth as reasons for restriction that the claims of each Group are structurally diverse and patentably distinct and one Group would not render any of the others obvious. An election of species within the Group elected was also required.

Applicants replied on May 2, 2005, electing with traverse Group IV and a species (without traverse). Applicants argued that the restriction was improper under the guidelines of *In re Weber* and M.P.E.P. 803.02 and that restriction within a claim was not permitted.

The examiner mailed a new Office action to applicants on June 21, 2005, acknowledging the election of Group IV and the traversal. The examiner maintained the requirement and made it Final on the basis of the reasons set forth in the previous Office action and that which applicants defined as the common core is too small or restrictive. The examiner also rejected claims 35-36 under 35 U.S.C. 112, first and second paragraphs, as lacking enablement and as indefinite. Claims 14-23 and 30-31 were rejected under 35 U.S.C. 102(b) as anticipated by Merla.

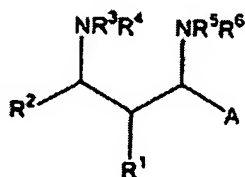
Applicants replied on October 21, 2005, by filing an amendment canceling claim 36, amending claims 14 and 35, and again traversing the restriction requirement for the same reasons and responding to each of the rejections of record.

The examiner mailed a Final Office action to applicants on December 22, 2005, maintaining the restriction requirement and rejecting claim 35 under 35 U.S.C. 112, first and second paragraphs, as lacking enablement and indefinite.

Applicants filed a request for reconsideration of the Final Office action on March 22, 2006, and this petition asking review of the restriction requirement. The examiner has not yet responded to the amendment after Final Office action.

DISCUSSION

Applicants' claims are directed to compounds having the structure of Formula I:



Applicants argue that the examiner has made an improper restriction requirement of the claims into twelve groups and argued that they represent different unrelated structures based on the above base structure. The examiner has done this by defining variables R₁ through R₆ and A.

A review of each of the variables shows that each may define specific alkyl, cycloalkyl, aryl and/or heteroaryl moieties. It is also possible for two variables to join together to form a ring fused to the base structure or the amino nitrogens, such as R₁ with R₂, R₃ with R₄ and R₅ with R₆, noting that the latter two rings are, of necessity, heterocyclic. The base structure applicants define as a 1,3 diamino propane compound. However, when R₁ and R₂ form a ring the compound is no longer a diamino propane, but an ortho-substituted aniline compound. Likewise, when R₃ and R₄ or R₅ and R₆ form a heteroring an N-substituted piperidine is formed. Each of these types of compounds is separately classified and bears no relationship to any others in structure or common physical properties.

Applicants argue initially that claim 1 is a proper Markush claim in that it satisfies the criteria set forth in *In re Harnish*, namely that the compounds encompassed must have a common utility and a substantial structural feature essential to that utility. Applicants argue that all compounds have utility as analgesics and that the substantial structural feature essential to the utility is the diamino propane portion of the compounds. However, as noted above, the propane portion may become part of a ring system and no longer exist as a substantial structural feature in all possible compounds (e.g. when R₁ and R₂ form a ring system incorporating a portion of the propane as part of the ring structure). It therefore cannot be considered the feature essential to utility of all compounds.

Further, where the substituted amino, either or both, form a heteroring the propane no longer is the significant structural feature, but the heteroring is the significant structural feature and controls or dictates the activity of the substituents attached to it to varying degrees.

Applicants argue that *In re Harnish* and *In re Weber* stand for the principle that applicants have a right to define their invention in the manner they choose and to have the entire invention examined. However they do not stand for the caveat, as applicants would argue, that restriction within a claim is improper. Where a Markush group encompasses multiple inventions, as here, it is proper for the examiner to require restriction between them based on the above noted principle of utility and substantial structural feature essential for that utility. Here it has been seen that what applicants' argue is the substantial structural feature does not exist in all structures and may not be the significant structural feature in all structures. Restriction is therefore justified.

A review of the examiner's restriction requirement, however, shows that it is inconsistent in some aspects and should be revisited and, if necessary, revised. The inconsistencies exist in that variable A is mentioned in only the first two Groups. As variable A has no direct effect on the essential structure, these two groups should be combined or eliminated. The remaining ten Groups are directed to where one or more of the pairs of R variables form or do not form a ring and whether that ring is heterocyclic. Essentially these can be as R₁ and R₂ – ring or no ring; R₃ and R₄ – no ring or heteroring or multiheteroring; and R₅ and R₆ – no ring or heteroring or multiheteroring. The combinations and permutations of these variables form 16 distinct Groups.

However where both substituted nitrogens form heterorings or multiheterorings, such compounds would likely fall into one group, thus reducing the number of groups to 12.

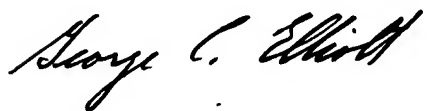
While a revised restriction requirement is not set forth herein, the examiner is encouraged to review and revise, as necessary, the restriction requirement along the lines indicated. It is noted that elected Group IV (and most of the other Groups set forth) is a proper Group within these guidelines.

DECISION

The petition is **DENIED** for the reasons set forth above.

The application will be forwarded to the examiner for consideration of the amendment after Final Office action filed March 22, 2006, and such other action as deemed appropriate.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 703-308-3824 or by facsimile sent to the general Office facsimile number, 571-273-8300.



George C. Elliott
Director, Technology Center 1600